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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|-----------------------|
| 10/829,427 | 04/22/2004 | Keisuke Furukawa | 252202US0 | 7267 |
| 22850 | 7590 | 05/09/2006 | EXAMINER | |
| OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314 | | | | WALICKA, MALGORZATA A |
| ART UNIT | | PAPER NUMBER | | |
| | | | | 1652 |

DATE MAILED: 05/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/829,427 | FURUKAWA ET AL. | |
| | Examiner | Art Unit | |
| | Malgorzata A. Walicka | 1652 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 12 April 2006.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 11 and 12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 11 and 12 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: sequence alignments.

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Amendment and Request for Reconsideration filed April 12, 2006 is acknowledged. Claims 1-10 have been canceled. New claims 11-12 have been added. The new claims read on the elected invention and are under examination.

DETAILED ACTION

2. Objections

2.1. Specification and drawings

Objections to the description of drawing is withdrawn in the light of Applicants explanations.

2.2. Claims

Objection to the language of claims 1-10 as not conforming to American practice is moot because the claims have been canceled.

New claim 11 is objected to, because part (e) recites "after 10-minute heat" which should be "after heating for 10 minutes".

3. Rejections

3.1. 35 U.S.C. 112, second paragraph

Rejection of claims 1-6 made in the Office action of 01/12/06 (previous action) is moot because the claims have been canceled.

New claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim is unclear in reciting "optional pH" and

"optional temperature". For examination purposes it is assumed that Applicant mean optimal pH and temperature.

In addition, claim 11(e) is rejected because the recitation "up to about 50° C makes it unclear if the protein must be stable at a only up to 50° C or near 50° C. A suggested language is "at about 50° C".

3.2. 35 USC section 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3.2.1. Written description

Claims 1-4 were rejected in the previous Office Action. This rejection is moot because the claims have been canceled.

New claim 12 is rejected under this paragraph, for lack of description of structure of broadly claimed genus of sarcosine oxidases obtained from SEQ ID NO: 1 by deletion, substitution, or addition of one or some amino acids retaining sarcosine oxidase activity. One skilled in the art realizes that a change of even one amino acids in

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a protein may turned a protein inactive or may change its activity. Providing the structure of SEQ ID NO: 1 does not identify the structural characteristics of the whole genus of sarcosine oxidases as encompassed by the broad scope of the claim.

In conclusion, one having skills in the art is not convinced Applicants were in possession of the claimed invention at the time the application was filed.

3.2.2. Scope of enablement

Claims 1-4 were rejected in the previous Office Action. This rejection is now moot because the claims have been canceled.

New claims 11 and 12 are rejected for lack of the enablement for the full scope of the claimed invention.

Claim 11 is directed to any modified sarcosine oxidase characterized by physico-chemical properties listed under a) to h), but this is not enabling for the structure of the claimed modified enzyme or at least the structure or origin of the enzyme that is to be modified. Although the method of modification of DNA molecules so that they encode modified enzymes, their expression and determination of sarcosine oxidase activity are well known in the art and the skills of artisans high, one who would like to make and use the invention is forced to experimentation with a low probability of success absent teaching the structures of modified sarcosine oxidases. While enablement is not precluded by the necessity for routine screening, if a large amount of screening is required, the specification must provide a reasonable amount of guidance with respect to the direction in which the experimentation should proceed so as to make and use the

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claimed invention; in this case at least the origin of the primary enzyme that is to be modified.

New claim 12 is rejected under this paragraph, because the specification, while being enabling for SEQ ID NO: 1 does not reasonably provide enablement for a sarcosine oxidase consisting of amino acid sequence obtained by modification of SEQ ID NO: 1, wherein the new sequence is obtained by deletion, substitution, or addition of one or some amino acids. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

While enablement is not precluded by the necessity for routine screening, if a large amount of screening is required, the specification must provide a reasonable amount of guidance with respect to the direction in which the experimentation should proceed as to make and use the claimed invention. Specifically, the specification does not provide any teachings or working example of how to modify SEQ ID NO: 1 so that the sequence after deletion, substitution, or addition of one or some amino acids retained sarcosine oxidase activity. One skilled in the art realizes that a change of even one amino acids in a protein may turned a protein inactive or may change its activity. Thus without teachings as to how to modify SEQ ID NO: 1 so that the modified protein retained the required activity a skilled artisan is forced to experimentation that has a low probability of success and is, therefore, undue.

3.3. 35 U.S.C. 102

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 12 is rejected under 35 U.S.C. 102(b) as being anticipated by Nishiya Y. et al. (Analysis of Interaction between the Arthrobacter Sarcosine Oxidase and the Coenzyme Flavin Adenine Dinucleotide by Site-Directed Mutagenesis, Applied and Environmental Microbiology, 1996, 62(7), 2405-2410 and over Japanese published Patent application JP05115281-A, published May 14, 1993.

Nishiya Y. et al. disclosed a modified sarcosine oxidase, obtained by modification of the sarcosine oxidase from Arthrobacter, wherein said modified sarcosine oxidase is in 85% identical to SEQ ID NO: 1 of the instant invention application. Rejection over Nishiya et al. applies to claims 12 part b) to the same extant as it applied to claim 6 in the previous Office action.

JP0511281 discloses Bacillus sarcosine oxidase that differs from SEQ ID NO: 1 of the instant application in positions 61 and 324. Thus, oxidoreductase of the Japanese document is in accord with the limitations of claim 12 part b); see the enclosed sequence alignment A.

3.4. Provisional obviousness double patenting

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The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 12 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 2 of copending Application No. 10/990,477, ('477). Although the conflicting claims are not identical, they are not patentably distinct from each other because SEQ ID NO:2 of the copending application which is clearly a preferred species that supports the genus of the copending application, anticipates claim 12 of this application; see alignment B.

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This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

4. Conclusion

Claims 11 and 12 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Małgorzata A. Walicka whose telephone number is (571) 272-0944. The examiner can normally be reached on Monday-Friday from 10:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Małgorzata A. Walicka, Ph.D.
Art Unit 1652
Patent Examiner


REBECCA E. PROUTY
PRIMARY EXAMINER
GROUP 1600
1600

A

Db 121 ||||||| GDEINTRWPGITVPENYNAIFEPNSGVLFSENCIRS YRELAVAKGAKILTYTRVEDFEVS 180
 Qy 181 QDQVKIQTANGSYTADKLIVSMGAWNSKLLSKLNLDIPLQPYRQVVGFFDSNEAKYSNDV 240
 |||||||
 Db 181 QDQVKIQTANGSYTADKLIVSMGAWNSKLLSKLNLDIPLQPYRQVVGFFDSNEAKYSNDV 240
 Qy 241 GYPAFMVEVPKG IYYGFPSFGGCGLKIGYHTYQQQIDPDTINREFGAYQEDESNL RDFLE 300
 |||||||
 Db 241 GYPAFMVEVPKG IYYGFPSFGGCGLKIGYHTYQQQIDPDTINREFGAYQEDESNL RDFLE 300
 Qy 301 KYMPEANGELKRGAVCMYT KTPDHVFIDTHPEHSNVFVAAGFSGHGFKFSSVVGEVLSQ 360
 |||||||
 Db 301 KYMPEANGELKRGAVCMYT KTPDHVFIDTHPEHSNVFVAAGFSGHGFKFSSVVGEVLSQ 360
 Qy 361 LATTGKTEHDISIFSINRPALKQKTTI 387
 |||||||
 Db 361 LATTGKTEHDISIFSINRPALKQKTTI 387

RESULT 2

AAR38078

ID AAR38078 standard; protein; 387 AA.

XX

AC AAR38078;

XX

DT 24-OCT-2003 (revised)

DT 26-JAN-1994 (first entry)

XX

DE Sarcosine oxidase M.

XX

KW SOM; creatinine; creatine; sarcosine; ss.

XX

OS Bacillus sp; KS-11A.

XX

PN JP05115281-A.

XX

PD 14-MAY-1993.

XX

PF 25-OCT-1991; 91JP-00280126.

XX

PR 25-OCT-1991; 91JP-00280126.

XX

PA (KIKK) KIKKOMAN CORP.

PA (NODA) ZH NODA SANGYO KAGAKU KENKYUSHO.

XX

DR WPI; 1993-251881/32.

DR N-PSDB; AAQ43507.

XX

PT New sarcosine oxidase M of specified aminoacid sequence - used for
PT enzymatic assay of creatinine or creatine.

XX

PS Claim 5; Page 10; 12pp; Japanese.

XX

CC The sarcosine oxidase M (SOM) has a high substrate specificity for
CC sarcosine and can be used in highly sensitive and specific enzymatic
CC assays for creatinine or creatine. The SOM is produced by incubating a
CC SOM-producing strain of Escherichia transformed by a vector comprising DNA
CC encoding SOM, in a culture medium and recovering SOM from the culture
CC medium. (Updated on 24-OCT-2003 to standardise OS field)

XX

A

SQ Sequence 387 AA;

Query Match 99.1%; Score 2026; DB 2; Length 387;
 Best Local Similarity 99.2%; Pred. No. 4.7e-186;
 Matches 384; Conservative 1; Mismatches 2; Indels 0; Gaps 0;

| | |
|----|--|
| Qy | 1 MSTHFDVIVVGAGSMGMAAGYYLAKQGVKLLVDAFDPPHTEGSHHGDTIIRHAYGEGR 60 |
| Db | 1 MSTHFDVIVVGAGSMGMAAGYYLAKQGVKLLVDAFDPPHTEGSHHGDTIIRHAYGEGR 60 |
| Qy | 61 (KVVPFALRAQE LWYELENETHNKIFTKTGVLVFGPKGESDFVAETMEAAEHSLTVDLLE 120 : |
| Db | 61 (KVVPFALRAQE LWYELENETHNKIFTKTGVLVFGPKGESDFVAETMEAAEHSLTVDLLE 120 |
| Qy | 121 GDEINTRWPGITVPENYNAIFEPNSGVLFSENCIRSYLELAVAKGAKILTYTRVEDFEVS 180 |
| Db | 121 GDEINTRWPGITVPENYNAIFEPNSGVLFSENCIRSYLELAVAKGAKILTYTRVEDFEVS 180 |
| Qy | 181 QDQVKIQTANGSYTADKLIVSMGAWNSKLLSKLNLDIPLQPYRQVVGFFDSNEAKYSNDV 240 |
| Db | 181 QDQVKIQTANGSYTADKLIVSMGAWNSKLLSKLNLDIPLQPYRQVVGFFDSNEAKYSNDV 240 |
| Qy | 241 GYPAFMVEVPKGIIYYGFPSSFGCGKLIGYHTYQQIDPDTINREFGAYQEDESNLRDFLE 300 |
| Db | 241 DYPAFMVEVPKGIIYYGFPSSFGCGKLIGYHTYQQIDPDTINREFGAYQEDESNLRDFLE 300 |
| Qy | 301 KYMPPEANGELKRGAVCMYT KTPDHHFVIDTHPEHSNVFVAAGFSGHGFKFSSVVGEVLSQ 360 |
| Db | 301 KYMPPEANGELKRGAVCMYT KTPDHHFVIDTHPEHSNVFVAAGFSGHGFKFSSVVGEVLSQ 360 |
| Qy | 361 LATTGKTEHDISIFSINRPALKQKTTI 387 |
| Db | 361 LATTGKTEHDISIFSINRPALKQKTTI 387 |

RESULT 3

AEB07361

ID AEB07361 standard; protein; 387 AA.

XX

AC AEB07361;

XX

DT 25-AUG-2005 (first entry)

XX

DE Novel modified Bacillus sarcosine oxidase (MSO) protein SeqID1.

XX

KW enzyme engineering; renal disease; sarcosine oxidase.

XX

OS Bacillus.

OS Synthetic.

XX

FH Key Location/Qualifiers

FT Misc-difference 115

/note= "Encoded by ATC"

FT Misc-difference 269

/note= "Encoded by TAT"

FT Misc-difference 315

/note= "Encoded by GCT"

XX

PN DE102004055686-A1.

XX

PD 23-JUN-2005.

B

RESULT 3
 US-10-990-477-2
 ; Sequence 2, Application US/10990477
 ; GENERAL INFORMATION:
 ; APPLICANT: KIKKOMAN CORPORATION
 ; APPLICANT: FURUKAWA, Keisuke
 ; APPLICANT: KAJIYAMA, Naoki
 ; TITLE OF INVENTION: MODIFIED SARCOSINE OXIDASES, MODIFIED SARCOSINE OXIDASE GENES,
 ; TITLE OF INVENTION: AND METHODS FOR PREPARING THE MODIFIED SCARCOSINE OXIDASES
 ; FILE REFERENCE: 261714US0
 ; CURRENT APPLICATION NUMBER: US/10/990,477
 ; CURRENT FILING DATE: 2004-11-18
 ; PRIOR APPLICATION NUMBER: JP 2003-387975
 ; PRIOR FILING DATE: 2003-11-18
 ; PRIOR APPLICATION NUMBER: JP 2004-184960
 ; PRIOR FILING DATE: 2004-06-23
 ; NUMBER OF SEQ ID NOS: 6
 ; SOFTWARE: PatentIn version 3.2
 ; SEQ ID NO 2
 ; LENGTH: 387
 ; TYPE: PRT
 ; ORGANISM: Artificial Sequence
 ; FEATURE:
 ; OTHER INFORMATION: Synthetic Construct

US-10-990-477-2

Query Match 98.6%; Score 2016; DB 39; Length 387;
 Best Local Similarity 98.7%; Pred. No. 2.4e-181;
 Matches 382; Conservative 1; Mismatches 4; Indels 0; Gaps 0;

| | |
|----|--|
| Qy | 1 MSTHFDVIVVGAGSMGMAAGYYLAKQGVKTLLVDADFPPHTEGSHGDTRIIRHAYGEGR 60 |
| | |
| Db | 1 MSTHFDVIVVGAGSMGMAAGYYLAKQGVKTLLVDADFPPHTEGSHGDTRIIRHAYGEGR 60 |
| Qy | 61 KYVPFALRAQELWYELENETHNKIFTKTGVLVFGPKGESDFVAETMEAAEHSLTVDLLE 120 |
| | : |
| Db | 61 EYVPFALRAQELWYELENETHNKIFTKTGVLVFGPKGESDFVAETMEAAEHSLIVDLLE 120 |
| Qy | 121 GDEINTRWPGITVPENYNAIFEPNSGVLFSENCIRSYLELAVAKGAKILTYTRVEDFEVS 180 |
| | |
| Db | 121 GDEINTRWPGITVPENYNAIFEPEPNSGVLFSENCIRSYLELAVAKGAKILTYTRVEDFEVS 180 |
| Qy | 181 QDQVKIQTANGSYTADKLIVSMGAWNSSLKLNLDIPLQPYRQVVGFFDSNEAKYSNDV 240 |
| | |
| Db | 181 QDQVKIQTANGSYTADKLIVSMGAWNSSLKLNLDIPLQPYRQVVGFFDSNEAKYSNDV 240 |
| Qy | 241 GYPAFMVEVPKGIIYYGFPSSFGCGLKIGYHTYQQIDPDTINREFGAYQEDESNL RDFLE 300 |
| | |
| Db | 241 DYPAFMVEVPKGIIYYGFPSSFGCGLKIGYHTYQQIDPDTINREFGAYQEDESNL RDFLE 300 |
| Qy | 301 KYMPEANGELKRGAVCMYT KTPDHVFIDTHPEHSNVFVAAGFSGHGFKFSSVVGEVLSQ 360 |
| | |
| Db | 301 KYMPEANGELKRGAAACMYT KTPDEHFVIDTHPEHSNVFVAAGFSGHGFKFSSVVGEVLSQ 360 |
| Qy | 361 LATTGKTEHDISIFSINRPALKQKTTI 387 |
| | |
| Db | 361 LATTGKTEHDISIFSINRPALKQKTTI 387 |